NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

REBECCA DANDY,

Plaintiff,

v.

ETHICON, INC., *et al.*,

Defendants.

Civil Action No. 20-431 (MAS) (DEA)

MEMORANDUM OPINION

SHIPP, District Judge

This matter comes before the Court on numerous motions in limine filed by Plaintiff Rebecca Dandy ("Plaintiff") and Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson (collectively, "Defendants"). Defendants filed six motions in limine (*see* ECF Nos. 121 to 126), with the first of those being an omnibus motion consisting of nine motions alone, and Plaintiff filed twelve motions in limine of her own (*see* ECF Nos. 127 to 138).[1] Each motion in limine was opposed. These motions in limine are in addition to one that the Court already addressed pertaining to expert testimony in the Honorable Chief Judge Freda L. Wolfson, U.S.D.J.-New Jersey (ret.),'s April 29, 2022 Memorandum Opinion (the "Second Opinion"). (*See generally* Second Op., ECF No. 95.) The Court has carefully reviewed the parties' submissions and decides the matter without oral argument under Local Civil Rule 78.1.

[1] After their filing, the parties agreed to terminate the motions at ECF Nos. 125, 127, and 129. (*See* ECF No. 167.)

I. BACKGROUND

The Court presumes the parties are familiar with the factual background and, accordingly, adopts the factual background as recited in the Honorable Robert F. Kelly, U.S.D.J.-Eastern District of Pennsylvania's December 13, 2019 Memorandum Opinion (the "First Opinion")[2] and the Second Opinion. (*See generally* First Op., ECF No. 9; Second Op.)

II. LEGAL STANDARD

The Court presumes the parties are familiar with the legal standard and adopts the legal standard set forth in the Second Opinion. (Second Op. 10-12.)

III. DISCUSSION[3]

A. Defendants' Motions in Limine

1. Defendants' Motion to Exclude Certain Opinions of Dr. Bruce Rosenzweig ("Dr. Rosenzweig")

Defendants move to exclude Dr. Rosenzweig from offering certain opinions. The Court addresses each in turn. (*See generally* Defs.' Dr. Rosenzweig Moving Br., ECF No. 122-2.)

a. Opinions that the multi-district litigation ("MDL") court excluded

First, Defendants contend that the Court should exclude Dr. Rosenzweig's opinions that the MDL court excluded. (*Id.* at 1.) Plaintiff asserts that Dr. Rosenzweig will not be offering the

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[2] The First Opinion transferred this action to the United States District Court for the District of New Jersey.

[3] "To expedite a ruling on th[ese] motion[s], the Court is communicating the reasons for its decision without attempting to draft a legal treatise or cite [all] relevant case law. The law in this area is clear and the Court has taken into account the authorities which are cited in the parties' briefs, along with other authorities. If necessary for future proceedings, the Court may supplement this [decision] with additional findings of fact or legal citations." *Kieffaber v. Ethicon, Inc.*, 529 F. Supp. 3d 1219, 1221 n.1 (D. Kan. 2021). Additionally, the Court presumes the parties are familiar with each other's respective briefing and, accordingly, the Court declines to summarize in full the arguments submitted by each party on each motion.

following opinions at trial: (1) "legal conclusion" testimony; (2) testimony concerning the level of Ethicon's testing; (3) Ethicon's "state of mind," or Ethicon's "corporate conduct" (from the standpoint of corporate state of mind/corporate ethics); or (4) the level of training Ethicon provided to physicians (including Plaintiff's implanting surgeon, Dr. William Nowak) regarding the use of the Tension-free Vaginal Tape-Obturator ("TVT-O"), so Defendants' arguments on these points are moot and should therefore be denied. (*See id.* at 2; Pl.'s Dr. Rosenzweig Opp'n Br. 4-5, ECF No. 166-1.) Seeing no disagreement between the parties, the Court denies this Motion as moot as to these points, yet reserves ruling as to the "summary of corporate documents," which the Court finds to be too vague to warrant a ruling at this juncture.

b. Opinions on degradation and deformation

Second, Defendants contend that Dr. Rosenzweig's degradation and deformation opinions do not fit the facts of this case and should be excluded. (Defs.' Dr. Rosenzweig Moving Br. 3-5.) Upon reviewing Dr. Rosenzweig's experiences and the bases for his opinions here, the Court finds that Defendants' objections, such as to the amount of data and materials upon which Dr. Rosenzweig relies for his opinions, are better suited for cross-examination. The Court finds persuasive the reasoning of the *Hosbrook* court, which in denying a similar motion by Defendants, explained that certain potential methodology defects identified by Defendants go to the weight to be given to the doctor's testimony. *See Hosbrook v. Ethicon, Inc.*, No. 20-88, 2021 WL 1599199, at *5 (S.D. Ohio Apr. 23, 2021) ("Defendants' motion to exclude the opinions of Dr. Rosenzweig on the subjects of mesh degradation and 'other alleged deformation' is overruled."). The Court denies the Motion as to this point.

c. Opinion on quality of life

Third, Defendants seek to preclude Dr. Rosenzweig from speculating about certain aspects of Plaintiff's continuum of care and quality of life because a lay jury could understand this opinion.

(Defs.' Dr. Rosenzweig Moving Br. 6.) The Court agrees with the finding of the court in *Thornton v. Ethicon Inc.*, 2022 WL 3139943, at *4 (D. Ariz. Aug. 5, 2022), which recently precluded Dr. Rosenzweig from offering these same opinions because "the proposed expert testimony regarding diminished quality of life was unnecessary because it is a concept that is understandable to the average juror." The Court grants the Motion as to this point.

d. Opinion on cut of TVT-O mesh

Fourth, Defendants contend that Dr. Rosenzweig's opinions that critique the ways in which TVT-O's mesh is cut should be excluded because they do not fit the facts of the case. (Defs.' Dr. Rosenzweig Moving Br. 6-7.) Upon reviewing Dr. Rosenzweig's opinions here, the Court agrees with the numerous courts that have previously found that Defendants' points as to Dr. Rosenzweig's opinions on the cut of the mesh are appropriate for cross-examination, not as a basis to exclude his testimony. *See, e.g.*, *Foster v. Ethicon, Inc.*, No. 20-04076, 2021 WL 4476642, at *11 (D.S.D. Sept. 30, 2021) ("This [c]ourt agrees with other courts that 'Dr. Rosenzweig's clinical experience with both laser-cut and mechanical-cut mesh is sufficient to satisfy the threshold reliability requirements of [Federal Rule of Evidence] 702.'") (citation omitted); *Olszeski v. Ethicon Women's Health & Urology*, No. 19-1787, 2022 WL 1063737, at *8 (N.D. Ohio Apr. 8, 2022) ("This prong of the motion is denied because the manner by which TVT-O mesh is cut still has relevance to the jury's risk utility analysis."). The Court denies the Motion as to this point.

e. Opinion on adverse events

Fifth, Defendants contend that the Court should preclude Dr. Rosenzweig from criticizing Ethicon's collection and reporting of adverse events, in compliance with a ruling by the MDL court that excluded such opinions, and because such opinions are beyond Dr. Rosenzweig's expertise and are not based on any reliable methodology. (Defs.' Dr. Rosenzweig Moving Br. 8.) Plaintiff replies that Dr. Rosenzweig will not offer any opinions at trial regarding Ethicon's collection of adverse event reports nor Ethicon's compliance with federal Food and Drug Administration's ("FDA") adverse event reporting regulations. (Pl.'s Dr. Rosenzweig Opp'n Br. 8-9.) Thus, the Court denies Defendants' Motion on these points as moot. (Pl.'s Dr. Rosenzweig Opp'n Br. 8-9.) Plaintiff, however, argues that "Dr. Rosenzweig should be permitted to provide opinions regarding Ethicon's *reporting* of adverse events and complications . . . as it directly goes to Plaintiff's punitive damages." (*Id.* (emphasis in original).) The Court finds, as the MDL court has ruled, that Plaintiff "may not use an expert 'solely [as] a conduit for corporate information.'" *See Heinrich v. Ethicon, Inc.*, No. 20-00166, 2021 WL 2290996, at *4 (D. Nev. June 4, 2021) (citation to internal record omitted) (excluding the same opinions by Dr. Rosenzweig). Thus, the Court grants Defendants' Motion as to those remaining points on this topic that are not rendered moot.

f. Opinion on warnings

Sixth, Defendants contend that the Court should exclude Dr. Rosenzweig's opinion that Ethicon did not properly warn of risks associated with TVT-O in its Instructions for Use ("IFU"), as these warning opinions do not fit the facts of the case. (Defs.' Dr. Rosenzweig Moving Br 9.) Given that the Court has already dismissed Plaintiff's failure to warn claim, the Court grants the Motion as to this point. (*See* Second Op. 37.)

2. Defendants' Motion to Exclude Testimony of Dr. Vladimir Iakovlev ("Dr. Iakovlev")

Defendants move to exclude Dr. Iakovlev from offering certain opinions. The Court addresses each in turn. (*See generally* Defs.' Dr. Iakovlev Moving Br., ECF No. 123-2.)

a. Opinions on degradation

Defendants first contend that the Court should exclude Dr. Iakovlev's degradation opinions, including his novel "bark" theory of degradation. (*See id.* at 4.) Specifically, Defendants contend that the "bark" theory is unreliable and not generally accepted. (See *id.* at 5-9.) Defendants further contend that his degradation opinions are unsupported by scientific literature and do not fit the facts of the case. (*See id.* at 9-13.)

"Other courts have addressed these arguments and found . . . that Dr. Iakovlev's 'bark theory' is not based on sound methodology (due largely to a lack of adequate testing), but that Dr. Iakovlev's other degradation opinions are admissible in that they are supported by other sources." *Enborg v. Ethicon, Inc.*, No. 20-02477, 2022 WL 800879, at *6 (E.D. Cal. Mar. 16, 2022), *reconsideration denied*, No. 20-02477, 2022 WL 1284868 (E.D. Cal. Apr. 29, 2022), *and on reconsideration*, No. 20-02477, 2022 WL 1651897 (E.D. Cal. May 24, 2022). The Court finds the reasoning of these "other courts" persuasive. *See, e.g.*, *Cutter v. Ethicon, Inc.*, No. 19-443, 2020 WL 2060342, at *6 (E.D. Ky. Apr. 29, 2020) (excluding Dr. Iakovlev's bark degradation testimony to the extent it is based on his "bark theory"); *Salinero v. Johnson & Johnson*, No. 18-23643, 2019 WL 7753453, at *8-10 (S.D. Fla. Sept. 5, 2019) (similar); *Kaiser v. Johnson & Johnson*, No. 17-114, 2018 WL 739871, at *3 (N.D. Ind. Feb. 7, 2018) (allowing Dr. Iakovlev "to testify regarding his degradation opinions generally" but finding "no evidence . . . to demonstrate that Dr. Iakovlev's 'degradation bark theory' [wa]s the product of reliable principles and methods"). The Court therefore grants Defendants' Motion to exclude as to Dr. Iakovlev's

"bark theory" of degradation but denies the Motion as to Dr. Iakovlev's other degradation opinions.

b. Opinions on clinical complications

Defendants next contend that the Court should exclude Dr. Iakovlev's opinions regarding clinical complications on the basis that they are unreliable. (*See* Defs.' Dr. Iakovlev Moving Br. 13-14.) The Court finds persuasive the reasoning of the MDL court, which addressed a substantially similar, if not the same *Daubert* motion, and found: "Dr. Iakovlev is a highly experienced clinical pathologist, and he is qualified to render his complications opinions based on his knowledge, skill, education, and experience." (*See In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig*. Order at 13, Ex. A, ECF No. 161-4.) Here, the Court agrees that the strength of Dr. Iakovlev's qualifications as well as the foundations for his opinions raised by Defendants are matters that go to the weight to be given to his opinions and are properly raised on cross-examination, not addressed through exclusion of his opinions altogether. "A witness may be qualified as an expert based on the witness's knowledge, skill, experience, training, or education." *Cantrell v. Coloplast Corp*., No. 20-0672, 2022 WL 2806390, at *6 (D. Minn. July 18, 2022). The Court denies Defendants' Motion as to this point.

c. Opinion on erosion

Next, Defendants contend that Dr. Iakovlev's opinion on the presence of an erosion and its implications should be excluded as unreliable and irrelevant. (*See* Defs.' Dr. Iakovlev Moving Br. 16-17.) Plaintiff states that she will not call or rely upon this opinion. (Pl.'s Dr. Iakovlev Opp'n Br. 4 n.2, ECF No. 161-1.) The Court, accordingly, denies the Motion as moot as to this point.

d. Opinions on mesh folding and deformation

Defendants contend that Dr. Iakovlev's opinions on mesh folding and deformation are unreliable and should, thus, be excluded. (*See* Defs.' Dr. Iakovlev Moving Br. 18-19.) Plaintiff

responds that she will not call or rely upon this opinion. (Pl.'s Dr. Iakovlev Opp'n Br. 4 n.2.) The Court, accordingly, denies the Motion as moot as to this point.

e. Opinions on mesh not at issue in this case

Defendants contend that Dr. Iakovlev should not be permitted to offer opinions based on mesh not at issue or mesh that he cannot identify. (*See* Defs.' Dr. Iakovlev Moving Br. 19-20.) Defendants, however, fail to identify any specific opinion given by Dr. Iakovlev in this case that Defendants contend depend solely or indefensibly upon a "data pool" including mesh not at issue or mesh that Dr. Iakovlev cannot identify—making it impossible to evaluate whether adequate support exists for the admission of such opinions. (*See id.* (contending broadly, for instance, that Dr. "Iakovlev seeks to explain his opinions using photographs of slides of mesh explants from various sources, many of which he has recycled from prior cases"). Thus, the Court reserves ruling on this Motion until trial.

f. Opinions on warnings

Defendants contend that the Court should exclude Dr. Iakovlev's opinions on Ethicon's warnings because he is not qualified to offer them and because they are irrelevant given that the Court has dismissed Plaintiff's warnings claim. (*See* Defs.' Dr. Iakovlev Moving Br. 20.) The Court agrees that its dismissal of Plaintiff's failure to warn claim renders Dr. Iakovlev's opinions on the sufficiency of Ethicon's warnings irrelevant. The Court grants the Motion as to this point.

3. Defendants' Motion to Exclude the Opinions and Testimony of Dr. Jimmy W. Mays ("Dr. Mays")

Defendants move to exclude Dr. Mays from offering certain opinions and testimony. The Court addresses each in turn. (*See generally* Defs.' Dr. Mays Moving Br., ECF No. 124-2.)

a. Opinions on degradation

Defendants first contend that the Court should exclude Dr. Mays' degradation opinions on the grounds that they are irrelevant and do not fit the facts of this case. (*See id.* at 2; *see also* Defs.'

Dr. Scott A. Guelcher ("Dr. Guelcher") Moving Br. 2-26, ECF No. 125-2 (setting forth Defendants' arguments that they adopt for this point).) The Court disagrees. Here, Dr. Mays' degradation opinions are directly relevant to Plaintiff's design defect claim because he opines specifically on, for example, the proper functioning of the mesh after implantation and the physical properties of polypropylene. (*See* Pl.'s Dr. Mays Opp'n Br. 7, ECF No. 155-1.) Such testimony will assist the triers of fact and comes from Dr. Mays' extensive experience with synthetic polymers. (*See id.* at 9-10.) Moreover, numerous other courts have denied similar requests by Defendants to exclude Dr. Mays' opinions on degradation. *See, e.g.*, *Arevalo v. Coloplast Corp.*, No. 19-3577, 2020 WL 3958505, at *8 (N.D. Fla. July 7, 2020*), aff'd sub nom. Arevalo v. Mentor Worldwide LLC*, No. 21-11768, 2022 WL 16753646 (11th Cir. Nov. 8, 2022). The Court denies the Motion as to this point.

b. Opinions on clinical complications

Second, Defendants contend that the Court should exclude Dr. Mays' opinions on clinical complications on the grounds that they are unreliable. (Defs.' Dr. Mays Moving Br. 2-3.) The Court agrees. Dr. Mays is not a medical doctor. (*See* Mays Dep. 3/2/16 at 53:4-7, Crawford Cert., Ex. C, ECF No. 124-1 ("I don't review medical records normally. I'm a polymer scientist. I'm a polymer chemist . . . . I'm not a medical doctor.").) He is also not a clinician. (*See id.* at 52:23-24.) Thus, the Court finds, in accordance with other courts, that Dr. Mays lacks the qualifications to offer opinions on the clinical complications allegedly caused by degradation. *See, e.g.*, *Arevalo*, 2020 WL 3958505, at *7 ("The Court finds that Dr. Mays is not qualified to offer opinions on medical complications because he is not a medical doctor."). While the Court finds that Dr. Mays may opine on how degradation affects mesh, he may not opine, for example, on the effects of such degradation on patients. The Court grants the Motion as to this point.

c. Opinions on Ethicon's knowledge, state of mind, corporate conduct, or legal conclusions

Defendants contend that Dr. Mays' opinions on Ethicon's knowledge, state of mind, corporate conduct, and legal conclusions should be excluded because they are improper expert testimony. (Defs.' Dr. Mays Moving Br. 4-6.) Plaintiff responds that Dr. Mays will not offer such opinions. (Pl.'s Dr. Mays Opp'n Br. 16.) The Court, accordingly, denies the motion as moot as to this point.

d. Opinions on dissimilar meshes

Defendants contend that the Court should exclude Dr. Mays' opinions based on a review of other meshes not similar to Plaintiff's implant because they are irrelevant and unreliable. (Defs.' Dr. Mays Moving Br. 6-7.) Specifically, Defendants seem to take issue with a study published in the *Biomaterials* journal that Dr. Mays co-authored pertaining to explanted mesh, hereinafter referred to as the "Imel study." (*Id.* at 6.) The Court is persuaded by the reasoning of the *Tyree* court, which found that the testing underlying the Imel study was unreliable. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 532-37 (S.D.W. Va. 2014); *see also Arevalo*, 2020 WL 3958505, at *7 (adopting the *Tyree* reasoning on this same issue). Thus, the Court grants the Motion in part. To the extent Dr. Mays' opinion is based solely on the Imel study, it is excluded. The Court denies the Motion to the extent that Dr. Mays is permitted to testify about his admissible opinions without referencing the data and conclusions reported in the Imel study.

e. Opinions on oxidation and degradation

In a somewhat repetitive argument, Defendants next contend that Dr. Mays' opinion that polypropylene "is continually attacked by strong oxidizing agents inside the body" should be excluded as unreliable because the articles on which Dr. Mays relies do not support this opinion. (Defs.' Dr. Mays Moving Br. 7-8.) Similarly, Defendants contend that Dr. Mays' opinion that

antioxidants "cannot permanently prevent" oxidation of polypropylene should be excluded as unreliable. (*Id.* at 9.) For the reasons set forth above regarding Dr. May's degradation opinions, the Court denies the Motion as to this point, which is better raised at cross-examination.

f. Opinions on toxicity

Finally, Defendants contend that Dr. Mays should be precluded from opining that the antioxidants in Prolene are toxic because such an opinion is unreliable given that it solely relies on statements in Material Safety Data Sheets ("MSDSs"). (Defs.' Dr. Mays Moving Br. 10-12.) Given that the Court partially denied a similar motion by Defendants pertaining to MSDSs as moot and reserved as to ruling on other aspects of that motion, *see supra*, the Court finds that this Motion, too, is more appropriate for trial. The Court reserves ruling on the Motion as to this point.

4. Defendants' Motion to Exclude the Opinions and Testimony of Dr. Peggy Pence ("Dr. Pence")

Defendants move to exclude Dr. Pence from offering certain opinions. The Court addresses Defendants' arguments in turn. (*See generally* Defs.' Dr. Pence Moving Br., ECF No. 126-2.)

a. Qualifications

Defendants first contend broadly that Dr. Pence is not qualified to opine on devices like TVT-O, citing to one court that has come to this conclusion. (*Id.* at 2 (citing *Martinez v. Coloplast Corp.*, No. 18-220, 2022 WL 425206, at *3 (N.D. Ind. Feb. 11, 2022).) Defendants ignore, however, the numerous other courts that have come to the opposite conclusion based on Dr. Pence's extensive experience as a specialist in medical device and pharmaceutical product development and regulatory affairs. (*See* Pl.'s Dr. Pence Opp'n Br. 7, ECF No. 156-1.); *see also Zetz v. Bos. Sci. Corp.*, No. 19-451, 2022 WL 17418450, at *7 (E.D. Cal. Dec. 5, 2022) (noting other courts that have found Dr. Pence qualified to testify in similar cases, including on regulatory issues); *Nunez v. Coloplast Corp.*, No. 19-24000, 2020 WL 2315077, at *6 (S.D. Fla. May 11, 2020) ("The Court sees no reason to second-guess the MDL [c]ourt's eight instances of finding

Dr. Pence qualified as an expert. [The company]'s *Daubert* motion to exclude the testimony of [Dr. Pence] is DENIED."). Indeed, Dr. Pence has a Ph.D. in toxicology, with a minor in pharmacology; although she has not worked on a clinical trial for a female pelvic-mesh device, she has implemented other clinical trials throughout her career. *Cantrell*, 2022 WL 2806390, at *6 (finding Dr. Pence specifically qualified to testify about the adequacy of a different pelvic mesh device's testing). In any event, "Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Id.* (citation omitted). Thus, the Court finds that Dr. Pence is qualified to render opinions on TVT-O.

b. TVT-O Opinion #1

Second, Defendants specifically contend that Dr. Pence is not qualified to render an opinion regarding what testing is required of TVT-O; that any such opinion is irrelevant given that additional testing is unrelated to the design defect claim at issue; and that, regardless, such an opinion is unreliable. (Defs.' Dr. Pence Moving Br. 4.) Dr. Pence opines that Ethicon failed to conduct appropriate testing to support safe and effective use of TVT-O. (Dr. Pence Expert Rep., Ex. A, ECF No. 126-5.) For the reasons set forth in the previous paragraph, the Court finds Dr. Pence qualified to render such an opinion. The Court, however, finds that such an opinion is not relevant considering that the Court has already dismissed Plaintiff's failure to warn claim. Thus, the Court grants the Motion as to this point.

c. Opinion #4 on post-market vigilance

Next, Defendants contend that Dr. Pence is not qualified to determine whether an adverse event should be reported to the FDA because she lacks the requisite medical judgment. (Defs.' Dr. Pence Moving Br. 7.) Additionally, Defendants contend that these opinions are unreliable, prohibited by federal law, irrelevant, unhelpful to the jury, and preempted. (*See id.* at 7-11.)

For the reasons set forth previously, the Court finds Dr. Pence qualified to render such an opinion. The Court also rejects Defendants' other arguments as to this opinion, many of which center on certain sources of Dr. Pence's opinions, such as the FDA's Manufacture and User Device Experience ("MAUDE") database or her reliance on Medical Device Reports ("MDRs"). (*See, e.g., id.* at 7 (Dr. "Pence's opinions about Ethicon's alleged failure to conduct post-market surveillance are unreliable because they are based solely on her review of the FDA's MAUDE database.").)[4] But Dr. Pence relies on multiple sources for post-market opinions here—not solely on one source, like the MAUDE database. (*See, e.g.*, Dr. Pence Expert Rep. 8, 94.) And numerous courts have rejected similar arguments by Defendants, with persuasive reasoning. *See Cantrell*, 2022 WL 2806390, at *9 ("[The Company]'s motion to exclude Dr. Pence's testimony based on her consideration of MAUDE data is denied."). Again, Defendants' arguments concern the factual bases of Dr. Pence's opinions, which go to weight and not admissibility. The Court denies the Motion as to this point.

d. Opinion #2 on TVT-O labeling

Defendants contend that Dr. Pence's opinion about labeling is irrelevant and inadmissible because the Court has already dismissed Plaintiff's warning claims, and that, even if they were relevant, Dr. Pence is not qualified to offer the opinion and it is unreliable. (Defs.' Dr. Pence Moving Br. 11.) Here, Dr. Pence opines primarily on the inadequacy of labeling for TVT-O, including the sufficiency of the IFU, and opine that the device was misbranded. (Dr. Pence Expert Rep. 103 (*e.g.*, "Ethicon marketed the TVT[-O] [s]ystem without adequate [IFU], in particular, without adequate warnings and information about potential risks.").) Because the Court has already dismissed Plaintiff's failure to warn claim, the Court finds that the opinion offered by Dr.

[4] MAUDE is a passive surveillance system. *See Cantrell*, 2022 WL 2806390, at *9.

Pence, including as it relates to whether TVT-O was misbranded, is irrelevant and would be confusing to the jury. *See Hosbrook v. Ethicon, Inc.*, No. 20-88, 2021 WL 4452289, at *7 (S.D. Ohio Sept. 29, 2021) ("barring any testimony, evidence or opinions regarding warnings," including testimony or evidence of a different surgical mesh device's IFU). The Court grants the Motion as to this point.

e. Opinion #3 on informed consent

Defendants similarly contend that Dr. Pence's opinion about informed consent is irrelevant and inadmissible because the Court has already dismissed Plaintiff's warning claims. (Defs.' Dr. Pence Moving Br. 21.) Here, Dr. Pence seeks to opine on the deficiencies in both patient labeling and professional labeling, including on the patient brochures for TVT-O. (Dr. Pence Expert Rep. 135.) For the reasons set forth in the previous paragraph, the Court finds that such testimony should be excluded on grounds of relevance. The Court grants the Motion as to this point.

5. Defendants' First Motion in Limine: To exclude certain irrelevant and unfairly prejudicial company documents and e-mail messages.

In their First Motion in Limine (as defined by Defendants), Defendants seek to exclude: (1) a 2003 e-mail string between Terry Courtney and Martin Weisberg discussing a TVT patient; (2) a 2004 e-mail string between Dan Smith and Janice Burns discussing the packaging for TVT and TVT-O; (3) a 2004 letter from Dr. Jakob Eberhard; (4) a 2002 e-mail chain discussing Prolene Soft Mesh; (5) two e-mail chains and related Dr. Meng Chen ("Dr. Chen") comments regarding warnings for the TVT family of products; (6) Brian Luscombe's "Top Ten Reasons to Pursue . . . Gynecare TVT Obturator System" Presentation; (7) the PA Consulting Group's 2011 Report "Investigating Mesh Erosion in Pelvic Floor Repair" ("PA Consulting Group Report"); (8) the 1997 Medscand License and Supply Agreement; and (9) a hernia mesh marketing video entitled

"The Benefits of Lightweight Meshes in Ventral Hernia Repair." (*See* Defs.' First Mot. 1-13, ECF No. 121-2.)

As to (1) the first e-mail string, the Court excludes it as irrelevant given that it discusses the experiences of another patient. *See Hosbrook*, 2021 WL 4452289, at *11 (excluding this email because it discussed a complication not alleged by the plaintiff). Accordingly, the Court grants the Motion as to this point.

As to (2) the 2004 e-mail string, the Court finds persuasive the reasoning of the *Kieffaber* court, which previously denied a similar request to exclude this same e-mail message because the court found it is "highly relevant to the issue of mesh degradation and what Ethicon knew about mesh degradation at the time of" Plaintiff's TVT-O sling implantation in 2011. (*See* Second Op. 3); *Kieffaber*, 529 F. Supp. 3d at 1222. Accordingly, the Court denies the Motion as to this point.

As to (3) the 2004 e-mail letter, the Court excludes it on relevance grounds given that it pertains to a "demo unit" rather than the device Plaintiff was implanted with. *See Jarrett v. Ethicon, Inc.*, No. 20-01517 (E.D. Ark. Sept. 23, 2022) ("*Jarrett* Sept. Order") 1, Crawford Cert., Ex. F, ECF No. 121-5 (excluding this evidence as irrelevant because the plaintiff was not implanted with a TVT demo unit); *Ruberti v. Ethicon, Inc.*, No. 20-874, 2022 WL 17875833, at *1 (M.D. Ala. Dec. 22, 2022) (similar). Accordingly, the Court grants the Motion as to this point.

As to (4) the 2002 e-mail chain, the Court finds persuasive the reasoning of the *Kieffaber* court, which previously denied a similar request to exclude this same e-mail message on the grounds that Defendants' arguments go to the weight, rather than admissibility, of the e-mail message. *See* 529 F. Supp. 3d at 1223. Accordingly, the Court denies the Motion as to this point.

As to (5) two email chains and related comments regarding warnings for the TVT family of products, the Court finds this evidence is irrelevant, as the Court has already dismissed Plaintiff's failure to warn claim. (*See* Second Op. 37 (granting summary judgment on Plaintiff's

failure to warn claim); *Smallridge v. Johnson & Johnson, et al.*, No. 20-248 (N.D.W. Va. Feb. 4, 2022) Hr'g Tr. ("*Smallridge* Hr'g Tr.") 128:16-129:1, Crawford Cert., Ex. C, ECF No. 121-5 (finding that this evidence was irrelevant because plaintiff's failure to warn claim had been dismissed); *Jarrett* Sept. Order 1-2 (finding that Dr. Chen's comments were "too intertwined" with product warnings to be admitted in a case with no failure to warn claim).) The Court, accordingly, grants the Motion as to this point.

As to (6) the "Top Ten Reasons to Pursue . . . Gynecare TVT Obturator System" Presentation, the Courts agrees with the numerous other courts that have excluded this testimony on the grounds, for example, that its risk of unfair prejudice outweighs any probative value to the claims in this case, and due to its potential to waste time during the trial. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 12-05201, 2014 WL 3861778, at *3 (S.D.W. Va. Aug. 6, 2014); *Edwards v. Ethicon, Inc.*, No. 12-09972, 2014 WL 3882186, at *4 (S.D.W. Va. Aug. 7, 2014). The Court, accordingly, grants the motion as to this point.

As to (7) the consulting report, the Court first finds that the PA Consulting Group Report is not hearsay, for it qualifies as either a statement "made by a person whom the party authorized to make a statement on the subject" or a statement "made by the party's agent . . . on a matter within the scope of that relationship and while it existed." Fed. R. Evid. 801(d)(2)(D). The Court also finds it relevant, in accordance with the findings of numerous other courts. *See, e.g.*, *Kieffaber*, 529 F. Supp. 3d at 1124 (concluding that the PA Consulting Group Report was "highly relevant" as "substantive evidence that the Prolift device design was defective" and the document was not "unduly prejudicial under [Federal Rule of Evidence] 403"); *Williams v. Ethicon, Inc.*, No. 20-234 (M.D. Ga. Feb. 25, 2022), ECF No. 237 (denying motion to exclude the PA Consulting Group Report). The Court denies the Motion as to this point.

As to (8) the 1997 Medscand License and Supply Agreement, the Court finds persuasive the reasoning of the MDL court, MDL No. 2327, which found that evidence about Professor Ulf Ivar Ulmsten's (the inventor of TVT) "financial interest is probative of the negligence and punitive damages claim and is not unduly prejudicial." *See Lewis v. Ethicon, Inc.*, No. 12-4301, 2014 WL 505234, at *7 (S.D.W. Va. Feb. 5, 2014); *Sutphin v. Ethicon, Inc.*, No. 14-01379, 2020 WL 5079170, at *8 (S.D.W. Va. Aug. 27, 2020). The Court, accordingly, denies the Motion as to this point.

Finally, as to (9) the hernia mesh marketing video, Plaintiff states that she "does not intend to offer this video into evidence at trial," so the Court, accordingly, denies the Motion as moot as to this point. (*See* Pl.'s Opp'n Br. to Defs.' First Mot. 12, ECF No. 159-1.)

In sum, the Court grants in part and denies in part Defendants' First Motion in Limine.

6. Defendants' Second Motion in Limine: This Court should exclude evidence of other lawsuits.

Defendants contend that evidence and argument of other pelvic mesh lawsuits is irrelevant, unfairly prejudicial and misleading, and inadmissible hearsay. (*See* Defs.' Second Mot. 13-15, ECF No. 121-2.) The Court notes that numerous other courts have excluded this type of evidence. *See, e.g.*, *Sutphin*, 2020 WL 5079170, at *6 ("Evidence of other lawsuits is likely to confuse and mislead the jury[], and it is highly prejudicial to Ethicon."); *Lewis*, 2014 WL 505234, at *6 (similar). Following the reasoning of these courts and finding that such evidence would lead to unfair prejudice and waste of time, the Court grants this Motion subject to the following requirements: Plaintiff shall not, absent prior leave of Court, introduce evidence or argument about unrelated lawsuits, claims, or investigations. But Plaintiff "may introduce any relevant admissions made by Ethicon in other lawsuits, claims, or investigations, to the extent the admissions would be admissible, including under [Federal Rules of Evidence] 801 or 803." *See Salinero v. Johnson & Johnson*, No. 18-23643, 2019 WL 7753445, at *3 (S.D. Fla. Sept. 25, 2019).

7. Defendants' Third Motion in Limine: This Court should exclude evidence and argument that Ethicon "rushed" TVT-O to market without conducting adequate premarket testing.

Defendants contend that evidence concerning the quality and quantity of testing Ethicon conducted prior to marketing TVT-O is irrelevant to Plaintiff's claims and that an inquiry into the reasonableness of Ethicon's conduct falls outside the understanding of a typical jury. (*See* Defs.' Third Mot. 15-16, ECF No. 121-2.) The Court disagrees. In particular, the Court finds instructive the reasoning of the court in *Williams*, which found, when analyzing a similar *Daubert* motion, that testimony on whether Ethicon researched or performed tests on problems associated with a pelvic mesh device is a "factual matter that does not implicate [Federal Rule of Evidence] 702." No. 20-234, 2021 WL 1087808, at *6 (M.D. Ga. Mar. 22, 2021). Here, the Court finds that Plaintiff should be allowed to present evidence addressing a manufacturer's testing as a matter of fact, rather than only as a matter of opinion testimony provided by an expert, for the Court finds that members of the jury do not need specialized knowledge to make a determination themselves on the sufficiency of the testing that occurred. The Court denies this Motion.

8. Defendants' Fourth Motion in Limine: This Court should exclude evidence and argument concerning the TVT-O warnings.

Defendants contend that because the Court has granted summary judgment to Defendants on Plaintiff's failure to warn claim, the adequacy of the TVT-O warnings is no longer at issue in this case. (Defs.' Fourth Mot. 17-18, ECF No. 121-2.) The Court agrees. Because the Court finds that evidence and arguments on warnings is irrelevant, the Court grants this Motion.

9. Defendants' Fifth Motion in Limine: This Court should exclude MDRs for other pelvic mesh patients.

Defendants move to exclude MDRs documenting reported adverse events of other pelvic mesh patients on the grounds that they are irrelevant and based on hearsay. (Defs.' Fifth Mot. 18-21, ECF No. ECF No. 121-2.) The Court finds persuasive and adopts the reasoning set forth in

Ruberti, 2022 WL 17875833, at *6, which recently examined a similar motion. Thus, the Court grants Defendants' Motion to exclude MDRs to the extent it seeks to exclude those submitted according to 21 U.S.C. § 360i(b)(1)(A), such as MDRs by hospitals and physicians who are not required to make reports.[5] In all other respects, the Court denies this Motion.

10. Defendants' Sixth Motion in Limine: This Court should exclude MSDSs for raw polypropylene.

Defendants move to prevent Plaintiff from introducing MSDSs published by the manufacturers of raw polypropylene on the grounds that such information is misleading and confusing to the jury. (Defs.' Sixth Mot. 21-22, ECF No. 121-2.) Plaintiff contends that she "does not intend to introduce evidence of any MSDSs for polypropylene other than that delivered to Ethicon and used in the manufacture of the TVT-O devices at issue in this case." (Pl.'s Opp'n Br. to Defs.' Sixth Mot. 1-2, ECF No. 160-1.) The Court denies this portion of the Motion as moot, but reserves ruling on this Motion to the extent Defendants seek to preclude other MSDSs, finding that the latter issue is more appropriate for trial.

11. Defendants' Seventh Motion in Limine: This Court should exclude evidence and references to foreign regulatory actions and other foreign issues.

Defendants move to exclude evidence and argument concerning foreign regulatory actions involving pelvic mesh products on the grounds that foreign regulatory actions are irrelevant to

[5] For more information on 21 U.S.C. § 360i(b)(1)(A), a statute that mandates MDRs in certain instances, *see Ruberti*, 2022 WL 17875833, at *5 (explaining that, generally, according to this statute, "evidence pertaining to MDRs submitted by a 'device user facility' or associated individuals, is not admissible. But the issue for [d]efendants is that there is no reason to think that other MDRs (like those submitted by manufacturers) are excludable"); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, 505 F. Supp. 3d 770, 780 (S.D. Ohio 2020) ("[M]anufacturer MDRs are admissible insofar as § 360i(b)(3) does not apply to them. Though no binding precedent is on point, the vast majority of courts to consider this question or similar ones have reached the same interpretation of § 360i(b)(3).").

Defendants' liability in this case, and that admitting this evidence at trial will waste time and confuse the jury. (*See* Defs.' Seventh Mot. 22-24, ECF No. 121-2.) Defendants further seek to specifically exclude evidence concerning alleged regulatory deficiencies in the clinical practices of Dr. Jean de Leval ("Dr. Leval"), the physician who developed TVT-O, as irrelevant and unfairly prejudicial. (*Id.* at 24-27.) The Court agrees with the numerous other courts who have examined the same or a substantially similar motion that an evidentiary ruling on the admissibility of foreign regulatory evidence would be premature at this stage, for Defendants seek to exclude a broad category of evidence in this motion. *See, e.g.*, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2013 WL 3282926, at *2 (S.D.W. Va. Jun. 27, 2013) ("In short, a blanket exclusion of such evidence or argument is premature at this time."); *Huskey*, 2014 WL 3861778, at *1 (similar). The Court, thus, reserves ruling on this Motion until trial.

12. Defendants' Eighth Motion in Limine: This Court should limit the use of mesh exemplars.

Defendants move to limit the in-court use of exemplar devices of mesh exemplars and preclude the jury from handling an exemplar or taking it to the jury room. (Defs.' Eighth Mot. 27-28, ECF No. 121-2.) In particular, Defendants seek to prevent Plaintiff's counsel and witnesses "from manipulating any exemplar mesh in a way that results in the mesh becoming twisted, stretched, distorted, folded, or damaged, which would give the jury a misleading impression about the mesh's physical qualities." (*Id.* at 27.) Defendants do not object, however, to the parties or their experts using mesh exemplars to show the jury what a device looks like. (*Id.*) Plaintiff explains how the jurors' ability to touch and examine the mesh will aid them in understanding the physical properties of TVT-O and the condition of the mesh prior to implantation into Plaintiff's body as well as the testimony of Plaintiff's experts regarding how the properties of the mesh changed after implantation. (Pl.'s Opp'n Br. to Defs.' Eighth Mot. 2, ECF No. 162-1.) Plaintiff contends that a simple instruction to the jurors that they may examine and touch the exemplar

mesh—but not manipulate it by pulling, tugging, twisting, etc.—is more than sufficient to address Defendants' concerns about distortions of the mesh, and Plaintiff "has no objection to any exemplars not going back with the jury to the jury room." (*Id.* at 3.) The Court agrees with Plaintiff and other courts that have found such stipulations as to the handling of exemplar devices under identical terms to be reasonable. (*See id.*; *see also Brennan v. Johnson and Johnson*, No. 20-01954 (C.D. Cal. Nov. 22, 2022) Stipulation, Ex. A, ECF No. 162-4.) Thus, the Court grants Defendants' Motion to the extent that Plaintiff's attorneys and witnesses may not manipulate the exemplar by twisting, stretching, folding, pulling on it, or otherwise handling it beyond holding it still, except that experts may manipulate the device as necessary to demonstrate how the implant procedure works; the Motion is also granted to the extent that the exemplar will not be sent to the jury room. The Court denies this Motion to the extent that the exemplar can be shown to and passed around by the jury, provided it is not sent back to the jury room. The jury will be instructed not to manipulate the device in any way.

13. Defendants' Ninth Motion in Limine: This Court should exclude evidence related to Plaintiff's punitive damages claim.

Defendants seek to preclude Plaintiff from presenting evidence supporting Plaintiff's punitive damages claim because Defendants contend such damages are not available to Plaintiff under controlling New Jersey law. (*See* Defs.' Ninth Mot. 28-35, ECF No. 121-2.) Defendants alternatively request that this Court preclude Plaintiff from referring to Defendants' net worth until the Court decides whether Plaintiff has made out a prima facie case for punitive damages." (*Id.* at 35.) Plaintiff contends that this Motion is an improper and untimely attempt to backdoor a summary judgment ruling and that, in any event, punitive damages are available under New Jersey law for medical devices reaching the market through the 510(k) process. (*See* Pl.'s Opp'n Br. to

Defs.' Ninth Mot. 4-6, ECF No. 165-1.) The parties agree that New Jersey law governs any potential punitive damages claim. (Final Pretrial Order *5, ECF No. 104.)[6]

The New Jersey Product Liability Act ("NJPLA") provides that punitive damages are not available in cases where the drug or medical device at issue in the case was "subject to premarket approval or licensure by the [FDA]" or "generally recognized as safe and effective pursuant to conditions established by the [FDA] and applicable regulations." N.J.S.A. § 2A:58C-5(c). Defendants contend that because TVT-O was cleared by the FDA under the Section 510(k) Premarket Notification process, which is the statutory framework by which the FDA clears all Class II medical devices to be marketed in the United States, Section 2A:58C-5(c) prohibits the recovery of punitive damages. (*See* Defs' Ninth Mot. 30-35.) Yet Defendants also "recognize that the New Jersey Superior Court Appellate Division has previously rejected the argument that the 510(k)-clearance process falls within the scope of Section 2A:58C-5." (*See id.* at 30-31.) At this time, the Court does not wish to diverge from the finding of the New Jersey Appellate Division in *Hrymoc v. Ethicon, Inc*, which previously concluded that punitive damages are available in cases involving devices that reach the market through the 510(k)-grandfathering process. *See* 249 A.3d 191, 215 (N.J. Super. Ct. App. Div. 2021). Indeed, numerous courts have likewise rejected Defendants' argument as it pertains to punitive damages under New Jersey law. *See, e.g.*, *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1020 (7th Cir. 2020); *Bellew v. Ethicon, Inc.*, No. 13-22473, 2014 WL 6674433, at *3-4 (S.D.W. Va. Nov. 24, 2014); *Parton v. Johnson & Johnson*, No. 18-419, 2021 WL 5154096, at *4 (E.D. Tenn. Sept. 14, 2021). The Court, thus, denies this Motion to the extent that the Court finds that the availability of punitive damages is best left to the determination of the jury. The Court grants this Motion, however, to the extent that the Court

[6] Page numbers preceded by an asterisk refer to the page numbers atop the ECF header.

agrees with Defendants that evidence of Defendants' net worth shall be excluded as unduly prejudicial until it is determined that Plaintiff has demonstrated that Defendants acted with the culpability necessary to impose punitive damages. *See Freeman v. Ethicon, Inc.*, No. 20-10661, 2022 WL 4604603, at *1 (C.D. Cal. Aug. 26, 2022) ("Numerous federal courts have excluded similar net worth evidence until it was determined that the plaintiffs had presented a prima facie showing of malice necessary to support an award of punitive damages.").

B. Plaintiff's Motions

1. Plaintiff's Motion to Exclude Certain General and Case-Specific Expert Opinions and Testimony of Dr. Shelby Thames ("Dr. Thames")

The Court turns now to the volley of motions filed by Plaintiff. Plaintiff first moves to exclude Dr. Thames from offering certain opinions. (*See generally* Pl.'s Dr. Thames Moving Br., ECF No. 128-2.) Specifically, Plaintiff takes issue with Dr. Thames's opinion that Prolene mesh, which Ethicon uses to manufacture its stress urinary incontinence ("SUI") devices, including TVT-O, does not degrade after implantation into the human body. (*See id.* at 1-2; *see also, e.g.*, Dr. Thames Case-Specific Rep. 11, Crawford Cert., Ex. A, ECF No. 145-2.) The Court addresses the arguments for exclusion raised by Plaintiff in turn.

a. 30(b)(6)

Plaintiff contends that Dr. Thames's opinions are barred by the Federal Rule of Civil Procedure 30(b)(6) deposition testimony of Thomas Barbolt ("Dr. Barbolt"), in which Dr. Barbolt admitted under oath that Prolene does undergo *in vivo* degradation. (*See* Pl.'s Dr. Thames Moving Br. 4; Barbolt Dep. Tr. 360:20-361:6, 385:14-20, 396:2-23, 409:2-13, Feldman Cert., Ex. F, ECF No. 128-8.) Primarily, Plaintiff contends that Dr. Thames's testimony, which "muddle[s] the testimony of its 30(b)(6) corporate designee," should be excluded as confusing and misleading to the jury. (*See* Pl.'s Dr. Thames Moving Br. 5.) But even assuming the veracity of Plaintiff's

contention, such a contradiction would not be enough to exclude Dr. Thames's opinions here. The Court finds particularly instructive the fact that numerous courts have examined and rejected Plaintiff's argument. *See, e.g.*, *Pitlyk v. Ethicon, Inc.*, No. 20-886, at 1-2 (E.D. Mo. July 7, 2021), Crawford Cert. Ex. D, ECF No. 145-5 ("The motion is DENIED insofar as the [c]ourt finds that . . . Ethicon is not bound by the admissions of its [Rule] 30(b)(6) witness Dr. . . . Barbolt, and DENIED insofar as the [c]ourt will not exclude Dr. Thames's opinions that contradict the testimony of Dr. . . . Barbolt."); *Mason v. Ethicon, Inc.*, No. 20-1078, 2021 WL 2580165, at *3 (M.D. Fla. June 10, 2021) ("Assuming Dr. Thames'[s] testimony contradicts the testimony of [d]efendants' 30(b)(6) witness, this is an insufficient basis to preclude Dr. Thames'[s] opinion."). Following this reasoning, the Court denies Plaintiff's Motion as to this point.

b. Opinions based on the dog study

Next, Plaintiff contends that the Court should exclude Dr. Thames's opinions on Prolene degradation and on Prolene's "toughness" because his statements misconstrue the findings from one of the Ethicon internal studies—the seven-year dog study. (*See* Pl.'s Dr. Thames Moving Br. 6-10.) While Plaintiff points to an MDL court determination about an outdated report offered by Dr. Thames in which he stated that the dog study reported "no changes" in molecular weight to support his conclusion that Prolene did not undergo harmful degradation *in vivo*, the Court finds that his report in this case does not contain such contradictions of the dog study to warrant exclusion. (*See id.* at 6-7.) Rather, Dr. Thames explains in his relevant general report that the dog study did not show a "meaningful" or "significant" change in the molecular weight of explants. (*See* Dr. Thames Gen. Rep, 6, 8-10, Crawford Cert., Ex. C, ECF No. 145-4.) Dr. Thames's compliance with the MDL court's prior order is not grounds to justify exclusion here. *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2016 WL 4608160, at *2 (S.D. W. Va. Sept. 2, 2016) (MDL court finding that Dr. Thames's "supposed self-contradictions"

do not warrant exclusion, including to the extent he uses the dog study to support similar Prolene-specific opinions).

Additionally, the Court rejects Plaintiff's contention that Dr. Thames has no basis for his opinion that the data from year seven of the dog study "validates toughness 'improvement' after initial implantation." (*See* Pl.'s Dr. Thames Moving Br. 8 (quoting Dr. Thames Gen. Rep. 9).) The Court finds persuasive the reasoning of other courts that have examined and rejected this argument before. *See In re Ethicon, Inc.*, 2016 WL 4608160, at *3 (finding that Dr. Thames "used a systematic method to plot data collected in the dog study on strength and elongation that could reasonably be said to relate to toughness"); *Olszeski v. Ethicon Women's Health & Urology*, No. 19-1787, 2022 WL 1121362, at *5 (N.D. Ohio Apr. 13, 2022) (similar).

Thus, the Court denies the Motion as to these points.

c. Opinions on translucent flakes

Plaintiff contends that Dr. Thames's "general and case-specific opinions regarding the presence of extrusion lines and translucent flakes on explanted mesh have no basis in the scientific method and no backing in the peer-reviewed literature," and, thus, they should be excluded as unsupported speculation. (*See* Pl.'s Dr. Thames Moving Br. 10.) Again, numerous courts have rejected this same argument, pointing out that these disputes by plaintiffs are more appropriately addressed by cross-examination. *See Olszeski*, 2022 WL 1063737, at *4-5; *Jarrett v. Ethicon, Inc.*, No. 20-1517, 2022 WL 4102489, at *1 (E.D. Ark. Sept. 7, 2022). The Court agrees with those courts' reasoning and, accordingly, denies Plaintiff's Motion as to this point.

d. Opinions on cleaning protocol

Finally, Plaintiff objects to Dr. Thames's opinions regarding "flawed cleaning protocol." (*See* Pl.'s Dr. Thames Moving Br. 12.) As the *Jarrett* court put it: "Again, this argument already has been rejected by the MDL court and is again rejected here. As has been noted before, this is

an issue for cross-examination." *Jarrett*, 2022 WL 4102489, at *1; *see also In re Ethicon*, 2016 WL 4608160, at *3. The Court denies the Motion as to this point.

2. Plaintiff's Motion to Limit the Opinions of Dr. Ted Roth ("Dr. Roth")

Plaintiff first moves to exclude Dr. Roth from offering certain case-specific and general opinions. (*See generally* Pl.'s Dr. Roth Moving Br., ECF No. 133-2.) The Court addresses each set of opinions in turn.

a. Opinions on pudendal neuralgia and pudendal nerve injuries

Plaintiff first contends that the Court should exclude Dr. Roth's various opinions concerning pudendal neuralgia, including his criticism of Dr. Michael Hibner's ("Dr. Hibner") diagnosis and treatment of Plaintiff's pudendal neuralgia, because he lacks the qualifications to render such opinions. (*See id.* at 4.) After reviewing Dr. Roth's background and experience, the Court disagrees. A witness may be "qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. The Third Circuit has "interpreted Rule 702's qualification requirement liberally," holding "that a broad range of knowledge, skills, and training qualify an expert." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (citations and quotations omitted). Dr. Roth is the Director of Urogynecology at Memorial Hospital, Beacon Health System, in South Bend, Indiana and an adjunct clinical professor at Indiana University School of Medicine. (*See* Dr. Roth CV, Crawford Cert., Ex. 1, ECF No. 147-2.) He is also Board certified in Obstetrics & Gynecology, with subspecialty Board certification in Female Pelvic Medicine and Reconstructive Surgery. (Dr. Roth Gen. Rep. 2, Crawford Cert., Ex. 2, ECF No. 147-3.) He describes in his General Report how he has "implanted about 1,200 midurethral slings in total," most of which are TVT-O. (*Id.* at 2.) And, perhaps most pertinently, he has testified that he has real-world experience "treat[ing] patients who have pudendal neuralgia in [his] practice" and the knowledge to recognize pudendal neuralgia in a patient who had a sling or pain after

surgery. (Dr. Roth Dep. Tr. 162:5-164:4, Crawford Cert. Ex. 4, ECF No. 147-5.) Plaintiff's complaint that Dr. Roth has never, for example, treated a patient who suffered pudendal neuralgia related to polypropylene mesh is the kind of qualification quibble that "goes to credibility and weight, not admissibility." (Pl.'s Dr. Roth Moving Br. 5); *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997). Furthermore, to the extent Plaintiff challenges their reliability, the Court finds such opinions reliable based on Dr. Roth's extensive experience, including firsthand knowledge. (*See* Pl.'s Dr. Roth Moving Br. 5.) The Court denies Plaintiff's Motion as to this point.

b. Opinions on Plaintiff's psychiatric history and history of abuse[7]

Plaintiff next contends that the Court should exclude Dr. Roth's opinions concerning Plaintiff's psychiatric history and history of substance abuse and sexual/physical abuse because he lacks the qualifications to offer them. (*See* Pl.'s Dr. Roth Moving Br. 6.) While Dr. Roth is not a psychologist or an equivalent, the opinions he seeks to offer are not to diagnose any mental health or substance abuse disorder in Plaintiff or the cause of such conditions. Rather, Dr. Roth considers Plaintiff's independently documented history of physical/sexual/substance abuse and mental illness, and opines about the likely impact of these conditions, in conjunction with other "multiple-pain generating conditions," on Plaintiff's current complaints of pelvic pain. (*See* Dr. Roth Case-Specific Rep. 22, Feldman Cert., Ex. A, ECF No. 133-5.) The Court finds that such opinions fall squarely within Dr. Roth's experience as a urogynecologist with a subspecialty in female pelvic medicine and reconstructive surgery, as explained above. Thus, the Court denies Plaintiff's Motion as to this point.

[7] As set forth later in this decision, Plaintiff may raise other objections regarding the introduction of this evidence at trial.

c. General FDA opinions

Finally, Plaintiff seeks to exclude Dr. Roth from offering opinions in his General Report that discuss various statements put forth by the FDA regarding pelvic mesh products. (*See* Pl.'s Dr. Roth Moving Br. 7.) For the reasons set forth below in the Court's analysis of Plaintiff's First Motion in Limine, the Court denies the Motion as to this point.

3. Plaintiff's Motion to Limit the Opinions of Dr. Peter Rosenblatt ("Dr. Rosenblatt")

Plaintiff also moves to exclude Dr. Rosenblatt from offering certain case-specific and general opinions. (*See generally* Pl.'s Dr. Rosenblatt Moving Br., ECF No. 138-2.) The Court addresses each set of opinions in turn.

a. Opinions on the safety and efficacy of mesh for "millions"

Plaintiff contends that the Court should exclude as unreliable Dr. Rosenblatt's opinions that mesh has been successful for "millions of women" given that he cites no studies for this proposition. (*See* Pl.'s Dr. Rosenblatt Moving Br. 3-6 (quoting Dr. Rosenblatt Dep. Tr. 80:15-19, Feldman Cert., Ex. B, ECF No. 138-7).) Dr. Rosenblatt explains that the basis for this statement is the position statement on mesh midurethral slings for stress incontinence issued by the American Urogynecologic Society ("AUGS") and Society for Urodynamics and Female Urology. (Dr. Rosenblatt Expert Rep. 107-08, ECF No. 138-5.) But courts have granted requests to exclude similar testimony where expert doctors cite to a position statement "in order to lend greater credence to [their] own opinion that the mesh is safe," even when they have "no background or experience similar to the doctors who crafted and issued those statements." *Wilichowski v. Bos. Sci. Corp.*, No. 21-5024, 2021 WL 1197795, at *10 (W.D. Ark. Mar. 29, 2021). Following such reasoning, the Court grants the Motion as to this point due to Dr. Rosenblatt's reliance solely on a position statement to inform his opinion.

b. Opinions on "fear mongering"

Next, Plaintiff contends that the Court should exclude as unreliable, speculative, and unfairly prejudicial Dr. Rosenblatt's opinions that the "fear mongering" surrounding mesh litigation has done a disservice to women. (*See* Pl.'s Dr. Rosenblatt Moving Br. 6-9 (quoting Dr. Rosenblatt Dep. Tr. 44:2-46:18).) Defendants respond that Dr. Rosenblatt "will not offer speculation on this topic; but to the extent he has experienced this phenomenon in his own practice, he should be allowed to testify as to that fact based on his own personal experience." (Defs.' Dr. Rosenblatt Opp'n Br. 6, ECF No. 146.) Because the Court sees no conflict between the Parties at this time, the Court denies the Motion on this point as moot.

c. Opinions on the physical properties of mesh

Plaintiff contends that the Court should exclude Dr. Rosenblatt's opinions on the physical properties of mesh, including shrinkage, porosity, and degradation, as unreliable. (*See* Pl.'s Dr. Rosenblatt Moving Br. 9-14.) The Court finds that Dr. Rosenblatt's opinions are sufficiently reliable. The Court finds particularly instructive the reasoning of the *In re C. R. Bard, Inc.* court, which found Dr. Rosenblatt qualified to offer similar observations on whether mesh degrades or shrinks based on, for example, his use of transvaginal mesh to treat pelvic organ prolapse for over ten years and extensive experience with polypropylene mesh. 2018 WL 605064, at *3. The Court denies the Motion as to this point.

d. Opinions on position statements

Finally, Plaintiff contends that the Court should exclude Dr. Rosenblatt's opinions on the various position statements issued by various medical organizations, including AUGS, on transvaginal mesh. (*See* Pl.'s Dr. Rosenblatt Moving Br. 14.) "[P]osition statements are not expert opinions." *In re C. R. Bard, Inc.*, 2018 WL 605064, at *4. The Court finds instructive the reasoning of the *Wilichowski* court, which found that while Dr. Rosenblatt may explain to the jury the

materials he reviewed and relied on in forming his own expert opinions, he may not "simply regurgitate the content of position statements issued by medical organization[s] as though they were his own opinions . . . [nor may he] testify in a matter that equates these position statements to his own medical opinions." 2021 WL 1197795, at *12. The Court grants Plaintiff's Motion as to this point.

4. Plaintiff's First Motion in Limine: To exclude evidence relating to activities of the FDA.

The Court now turns away from Plaintiff's *Daubert* motions and toward what Plaintiff generally labels as motions in limine. In Plaintiff's First Motion in Limine, Plaintiff asks the Court to exclude evidence or argument relating to the FDA's 510(k) clearance of Ethicon's mesh products or lack of FDA enforcement actions relating to Ethicon's mesh products, and reference to any FDA advisory committee. (Pl.'s First Mot. 2, ECF No. 130-2.)[8] Plaintiff contends that such evidence or argument risks misleading the jury, confusing the issues, and unfair prejudice. (*Id.* at 3.) The Court acknowledges that numerous courts in the MDL litigation have found that evidence relating to the 510(k) process should be excluded on grounds such as irrelevance and improperly confusing the jury. (*See id.* (citing the courts excluding such evidence).) Yet in this case, Michigan law controls. (*See* Second Op. 10.)

Here, the FDA's clearance of TVT-O is relevant to the elements of the design defect claim. *See Palatka v. Savage Arms, Inc.*, 535 F. App'x 448, 451-52 (6th Cir. 2013) (outlining elements of design defect claim in Michigan). Under Michigan law, a manufacturer is entitled to a rebuttable presumption of no liability if the product "was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state

[8] The FDA's "510(k) review process originates from the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1317 (11th Cir. 2017). For more information on this process, *see generally id.*

agency responsible for reviewing the safety of the product" at the time the specific unit at issue was sold or delivered to the initial purchaser or user. *See* Mich. Comp. L. Ann. § 600.2946(4); *Lavin v. Child Craft Indus., Inc.*, No. 245386, 2004 WL 840230, at *2 (Mich. Ct. App. Apr. 20, 2004) ("There is a rebuttable presumption that a manufacturer is not liable if the product was in compliance with government regulations at the time the product was sold. While failure to comply is relevant to proving negligence, it does not raise a presumption of negligence."). Courts applying Michigan law have held that a medical device manufacturer may invoke Section 600.2946(4)'s presumption where the product in question was cleared by the FDA at the time it was sold. *See Teal v. Argon Med. Devices, Inc.*, 533 F. Supp. 3d 535, 552 (E.D. Mich. 2021) ("Under [Section 600.2946(4)], a manufacturer of an implantable medical device is entitled to a presumption of no liability where the device was cleared by the FDA and subject to comprehensive FDA regulations applicable to its design and manufacture. The existence of a rebuttable presumption requires a plaintiff to offer admissible evidence to rebut the presumption."). The 510(k) equivalence process is one such FDA regulatory process. Plaintiff may present arguments on the robustness of this process to the jury and may seek a limiting instructing that 510(k) clearance does not preclude Plaintiff's claims. (*See White v. Ethicon, Inc.*, No. 20-952 (Mar. 21, 2022), Hr'g Tr. 3-4, Crawford Cert., Ex. 2, ECF No. 148-3 (denying similar motion in limine after finding that Washington law, like Michigan law, permits a jury to consider evidence that the product complied with relevant government standards, and noting that the plaintiff could request a limiting instruction explaining the meaning of 510(k) clearance).) Such arguments on the 510(k) process may also be relevant to Plaintiff's punitive damages claim. *See Hrymoc*, 249 A.3d at 202-13. Further, the Court is not convinced that such information will be unduly confusing to the jury. The Court, accordingly, denies the Motion as to this point.

Plaintiff also seeks to preclude any reference to FDA Advisory Committee recommendations. (*See* Pl.'s First Mot. 4-5.) The Court finds persuasive the reasoning of the *Nunez* court, which found that such FDA Advisory Committee recommendations "fail the [Federal Rule of Evidence] 403 balancing test and are inadmissible hearsay." 2020 WL 2315077, at *11. Like the *Nunez* court, however, and other courts before it, Defendants can introduce the underlying studies relied on by the FDA Advisory Committee, assuming Defendants lay a proper foundation for admissibility. *See id.*; *see also Salinero v. Johnson & Johnson*, No. 18-23643, 2019 WL 7753438, at *9 (S.D. Fla. Sept. 25, 2019); *Huskey v. Ethicon, Inc.*, 848 F.3d 151, 161 (4th Cir. 2017). The Court grants the Motion as to this point.

Next, Plaintiff seeks to preclude any suggestion that Ethicon required FDA consent to issue warnings or otherwise protect consumers, on the grounds that this suggestion is unfounded and misleading. (Pl.'s First Mot. 4-5.) "Plaintiff anticipates that Ethicon may suggest to the jury that: (1) it was not able to change its labeling to add a warning to the IFU accompanying its TVT-O absent FDA consent to such language; (2) it could not otherwise warn physicians without FDA approval (*e.g.*, through "Dear Doctor" letters); and/or (3) it required FDA approval prior to any recall or discontinuance of its TVT-O sales." (*Id.*) The Court finds, however, that such evidence is not relevant given that the Court has already excluded Plaintiff's failure to warn claim. In any event, Defendants assert that they "do not intend to offer any evidence concerning the FDA's regulation of medical device warnings." (Defs.' Opp'n Br. to Pl.'s First Mot. 29, ECF No. 148.) The Court denies the Motion as to this point.

Finally, Plaintiff seeks to exclude legal opinions by exert witnesses, including opinions on the meaning of regulations promulgated by the FDA. (Pl.'s First Mot. 7.) Defendants respond that they "do not intend to offer any evidence concerning what the FDA's state of mind [is] or what it 'understood.'" (Defs.' Opp'n Br. to Pl.'s First Mot. 30.) Thus, the Court denies the Motion as moot

as to this point and denies the remainder of Plaintiff's Motion on Ethicon's anticipated defenses as premature at this stage.

5. Plaintiff's Second Motion in Limine: To exclude references to the fault of non-parties or alternative causes absent competent evidence of unforeseeability.

Absent any showing that negligence of a non-party was entirely unforeseeable and unexpected and would exclude the negligence of Defendants, Plaintiff moves to preclude Defendants from offering any suggestion that the physician who implanted the TVT-O device or any other treating physician (or non-party) committed any act of negligence. (Pl.'s Second Mot. 1-2, ECF No. 134-3.) At this time, the Court finds that such a request by Plaintiff is too vague to warrant ruling, given that Plaintiff does not identify any specific evidence that would be excluded if the Court were to grant her Motion. *See, e.g., Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) (stating motions in limine that "exclude broad categories of evidence should rarely be employed"). Thus, the Court reserves ruling on this Motion.

6. Plaintiff's Third Motion in Limine: To exclude evidence that the TVT product line is still on the market.

Plaintiff next seeks to preclude any suggestions that Ethicon's TVT-product line (including TVT-O) is still on the market for the same reasons Plaintiff cites for Plaintiff's First Motion in Limine concerning evidence of FDA approval activities. (Pl.'s Third Mot. 1-2, ECF No. 135-3.) Plaintiff's concern is that statements that the product remains on the market are a "backdoor way of telling the jury that the FDA has approved the product or endorses its safety and efficacy." (*Id.* at 2.) For the reasons set forth in the Court's denial of Plaintiff's arguments on the 510(k) process within Plaintiff's First Motion in Limine, the Court denies this Motion.

7. Plaintiff's Fourth Motion in Limine: To exclude evidence that insinuates Plaintiff sought medical treatment for litigation purposes and limiting testimony of treating physicians.

Plaintiff contends that the testimony of all treating physicians in this case should be limited to "that which is related to and learned through actual treatment of the patient and which is based on his or her personal knowledge of the examination diagnosis and treatment." (Pl.'s Fourth Mot., 2, ECF No. 131-2.) Plaintiff, however, does not identify any treating physician testimony from this case that would violate this limitation. (*See generally id.*) To the extent the parties have specific objections to any statements by treating physicians, the Court finds that the best way to resolve those disputes is through objections to deposition designations or contemporaneous objections at trial. Because the Motion as written is impermissibly vague and overbroad, the Court reserves ruling on this Motion.

8. Plaintiff's Fifth Motion in Limine: To exclude arguments, evidence, or testimony about money paid to experts.

Plaintiff next seeks to preclude evidence of Plaintiff's experts' total compensation earned serving as experts in transvaginal and pelvic mesh litigation as a whole on the grounds that such evidence confuses the issues and misleads the jury. (Pl.'s Fifth Mot. 1, ECF No. 136-3.) Notably, Plaintiff concedes that generally, such testimony is admissible, yet contends that the "unique circumstances of this case" warrant reconsideration of the general rule. (*Id.* at 1-2.) The Court acknowledges that several other courts have examined and rejected Plaintiff's same arguments. (*See Richards v. Ethicon, Inc.*, No. 21-00092 (E.D. Tex. Sept. 13, 2022) Order 2, Crawford Cert., Ex. 2, ECF No. 152-3 (granting in part and denying in part plaintiff's motion in limine to exclude evidence of total expert compensation); *Jarrett* Sept. Order 3 ("How much an expert is paid is fair game.").) The Court agrees that evidence of an expert's compensation is probative of that expert's credibility and bias, which is an appropriate subject for impeachment. The Court, however, finds

that evidence of the compensation of experts who *do not* testify in this case is not relevant. *See United States v. Abel*, 469 U.S. 45, 51, 54 (1984). Plaintiff also briefly mentions a coterie of other unrelated points regarding general expert testimony that she seeks to preclude as irrelevant and misleading. (Pl.'s Fifth Mot. 2.) Those issues are better suited for contemporaneous objections. The Court, accordingly, grants this Motion in that Defendants shall not present testimony relating to the compensation of any experts not called to testify in this case, but denies this Motion in all other respects.

9. Plaintiff's Sixth Motion in Limine: To exclude evidence or testimony of Plaintiff's personal information, including certain irrelevant medical/surgical information and social history.

Plaintiff next seeks to exclude evidence or testimony of Plaintiff's personal information, including certain irrelevant medical/surgical information and social history, as irrelevant and unfairly prejudicial, confusing to the jury, and a waste of time. (Pl.'s Sixth Mot. 1-2, ECF No. 137-3.) In her initial briefing, Plaintiff seeks to prohibit any reference to the following topics: "Plaintiff's prior marriages and the nature of those relationship(s), divorce(s), family issues; any unrelated and/or irrelevant surgeries, injuries, disabilities or illnesses; information relating to when and why Plaintiff contacted and hired counsel; information relating to Plaintiff's social media activity including Facebook, Instagram, Twitter, and other platforms." (*Id.* at 2.) On February 10, 2023, Plaintiff submitted supplemental briefing two weeks after the motion in limine deadline of January 27, 2023 (*see* ECF No. 114), which added eight new categories of information Plaintiff further wishes to exclude: injuries, including left orbital and rib fractures, resulting from a February 2018 motor vehicle accident; the circumstances surrounding said motor vehicle accident, including Plaintiff's intoxication and subsequent DWI conviction; Plaintiff's history of shoulder injuries, including injuries resulting from an incident with a family member wherein Plaintiff was pushed to the ground; prior disputes with family members, including an incident in or around May

2017 that arose at a family birthday party; Plaintiff's history of bulimia; Plaintiff's history of physical, emotional, and/or sexual abuse, as well as any resulting post-traumatic stress disorder; Plaintiff's history of suicide attempt(s); and references to alcohol or drug use on the part of Plaintiff. (*See* Pl.'s Sixth Mot. Suppl. Br. 2-3, ECF No. 143.)

In neither her initial briefing nor her supplemental briefing, however, does Plaintiff detail exactly which evidence or testimony she wishes to exclude within these categories; instead, in a two-page brief, she seeks to categorically exclude all such evidence or testimony within these categories. Because the Court finds that this Motion is too vague and overbroad to warrant a ruling, the Court reserves ruling on this Motion until trial.

10. Plaintiff's Seventh Motion in Limine: To exclude argument, evidence, or testimony regarding other mesh and patients.

Finally, Plaintiff seeks to exclude three categories of argument, evidence, or testimony regarding other mesh and patients. (Pl.'s Seventh Mot. 1, ECF No. 132-2.) Plaintiff first seeks to exclude argument, evidence, or testimony regarding the number of women allegedly treated with mesh for stress urinary incontinence as speculative, misleading, unfairly prejudicial, and irrelevant. (*Id.* at 1-2.) Second, Plaintiff seeks to exclude statements regarding the number of randomized controlled trials that allegedly support the safety of TVT-O as inadmissible hearsay, confusing to the jury, a waste of time, unfairly prejudicial, and unreliable. (*Id.* at 2-4.) Third, Plaintiff seeks to exclude argument, evidence, or testimony relating to the general population use of polypropylene and transvaginal mesh products on the grounds of irrelevancy, unfair prejudice, inefficiency, and that such statements would be misleading and confusing to the jury. (*Id.* at 5-6.) As for the latter point, Plaintiff seeks to specifically exclude anticipated argument, evidence, and or/testimony from Ethicon that (1) transvaginal mesh products, mid-urethral slings and/or TVT-O are used by "X Number" or "X Percentage" of doctors all over the country/world, and (2) pelvic mesh and/or

TVT-O has been "implanted in millions of women around the world" (or similar such argument). (*Id.*)

Beginning with the first category, the Court finds persuasive the reasoning of the *Nunez* and *Salinero* courts, which found that similar evidence and testimony would allow for highly speculative numbers and essentially create "'mini-trials' on the experiences of many other women and the various products they received in surgeries." *See Nunez*, 2020 WL 2315077, at *10-11 ("The Court agrees that such a statement and any related testimony are speculative and flatly impossible to prove."); *Salinero*, 2019 WL 7753438, at *8 (explaining that "[s]uch testimony is likely to be more prejudicial than probative"). The Court, accordingly, grants Plaintiff's Motion on this point.

As for the second category, the Court finds persuasive the reasoning of the *Kieffaber* court, which previously examined and denied a similar motion as it pertained to a different pelvic mesh device. *See Kieffaber v. Ethicon, Inc.*, No. 20-1177, 2021 WL 1177914, at *1 (D. Kan. Mar. 26, 2021). Defendants correctly note that the randomized controlled trials themselves qualify as learned treatises under Federal Rule of Evidence 803(18); to the extent Defendants' experts relied on randomized controlled trials in forming their opinions in this case, evidence about the trials is not hearsay. (Defs.' Opp'n Br. to Pl.'s Seventh Mot. 4-5, ECF No. 154.) Similarly, nothing about the sheer "number" of such trials is inherently prejudicial or subject to exclusion under Federal Rule of Evidence 403. *See Lewis*, 2014 WL 505234, at *1 (finding that a statement about the number of randomized controlled trials is "not hearsay"). Obviously, Plaintiff can cross-examine to find out whether each randomized controlled trial in the number referenced concerns TVT-O and whether the study actually supports a finding that it is safe and efficacious. *See Kieffaber*, 2021 WL 1177914, at *1. To facilitate that cross-examination and avoid wasting the time of jurors and witnesses, the Court orders that no later than 5:00 p.m. within five days of the date of the issuance

of this Memorandum Opinion, Defendants identify for Plaintiff "each randomized controlled trial on which their experts intend to rely in counting them up at trial." *See id.* Subject to these requirements, the Court denies Plaintiff's Motion as to this point.

As for the third category, the Court finds that Plaintiff's arguments here essentially mirror those presented in regard to the first category. The Court grants the Motion as to this point for the reasons set forth above.

IV. CONCLUSION

For the reasons stated above, the Court grants in part, denies in part, and defers in part Plaintiff's and Defendants' motions in limine. The Court will enter an Order consistent with this Memorandum Opinion.

/s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE